IN THE
UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MAINE

CASE NO. _____

IMS HEALTH INCORPORATED; VERISPAN, LLC; and SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of WOLTERS KLUWER, HEALTH INC.,	
Plaintiffs,	PRELIMINARY & PERMANENT INJUNCTIVE RELIEF SOUGHT BEFORE JAN. 1, 2008
vs.	
STEVEN ROWE, as Attorney General of the State of Maine,	
Defendant.	

Complaint for Declaratory & Injunctive
Relief with Respect to Maine Public Law 2007, Chapter 460

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INTRODUCTION

Plaintiffs, IMS Health Incorporated, Verispan LLC, and Source Healthcare Analytics, Inc., sue the defendant, Steven Rowe, as Attorney General of the State of Maine, and state:

1. This is an action to declare portions of Maine Public Law 2007, Chapter 460, which amends 22 M.R.S.A. §§ 1711-E, 8704 and 8713 (2007) (hereinafter "the Prescription Restraint Law"[1] or "the law"), unconstitutional and to preliminarily and permanently enjoin its enforcement.[2] The law violates the First and Fourteenth Amendments of the United States Constitution by prohibiting the license, use, sale, transfer, or exchange for value of lawfully-obtained, truthful, important information without directly advancing important or substantial government interests when alternatives that do not restrict speech are available to achieve the state's objectives. The law also violates the Commerce Clause of the United States Constitution by regulating transactions that take place wholly outside of Maine.

2. Plaintiffs, the "health information publishers," are the world's leading providers of information, research, and analysis to the pharmaceutical and health care industries. Plaintiffs provide a vital link between physicians and pharmaceutical manufacturers, medical researchers, health economists and regulatory agencies – a link that helps improve public health and ensure patient safety through the collection, analysis, and reporting of vast amounts of information regarding the drugs that doctors prescribe. For more than a decade, this work has helped to ensure that the right doctors receive the right information about the right drugs so that the doctors can make the right choices for their patients. At the same time, this work always has

[1] The official title is "An Act To Amend the Prescription Privacy Law." Plaintiffs use a different title for purposes of brevity and to emphasize that the effect of the law is to restrain publication of prescription information.

[2] A copy of Public Law, Chapter 460, 123rd Maine State Legislature (2007), is attached hereto as Exhibit A.

safeguarded patient privacy.

3. Last year, the state of New Hampshire enacted an extraordinary law – the first of its kind in the United States – that attempted to put an end to this work by prohibiting pharmacies and similar entities from communicating lawfully-obtained, truthful information about doctors' prescribing practices in prescription records. The State of New Hampshire enacted the law on the basis of speculation that restricting targeted marketing by pharmaceutical companies by cutting off the flow of information about doctors' prescribing practices would lower healthcare costs in that state. The State also passed the law in order to keep physician prescription decisions from public scrutiny.

4. Two of the plaintiffs in this suit challenged the constitutionality of the New Hampshire law because the prohibition against communications concerning the prescription decisions of New Hampshire doctors violated the health information publishers' First Amendment Rights without directly advancing a substantial governmental interest and because the state had other alternative means to achieve its goals without infringing on the health information publishers' First Amendment rights.

5. At the same time that the New Hampshire district court was considering the New Hampshire law, the Maine Legislature took steps to enact similar legislation. L.D. 4 (2007), as originally proposed, was modeled after and was almost identical to the New Hampshire Prescription Restraint Law.

6. Before the Maine law was enacted, however, the New Hampshire district court declared the New Hampshire law unconstitutional and permanently enjoined its enforcement. *See IMS Health Inc. v. Ayotte,* 490 F. Supp. 2d 163 (D.N.H. April 30, 2007), *appeal docketed*, No. 07-1945 (1st Cir. June 20, 2007).

7. The Maine Legislature then hastily amended its bill to try to address the constitutional defects found in the New Hampshire legislation. Instead, it made the Maine legislation even more constitutionally suspect by vesting in prescribers themselves the decision as to whether the speech of third parties will be restrained. This increases the danger that the law will be used to shield poor prescribing practices and that this will increase, rather than decrease, the rising costs of healthcare. In addition, legislative findings were hastily added to the Maine bill only after the New Hampshire court ruled that a legislative body is not entitled to deference when it does not make findings. The so-called "findings" are little more than conclusory statements based on no actual evidence of any connection between the supposed ill the law is intended to cure – rising drug costs – and the publication of truthful prescribing information conveyed by entities such as the plaintiffs.

8. The American Medical Association, which opposes restrictions on the collection and disclosure of physician prescribing data, has observed that this information "is critical to improving the quality, safety and efficacy of pharmaceutical prescribing through evidence-based medical research." Just as critical, the Maine law also goes against the national movement toward more transparency in healthcare practices, as observed in legislative testimony by the Maine Medical Association, which opposed the law's enactment. The success of initiatives designed to improve healthcare quality, ensure patient safety and manage costs depends on publication of more information – not less. Without the right to publish prescriber-identifiable data, the healthcare community will lose a powerful tool to help monitor the safety of new medications and ensure that patients taking them are not harmed. Without such information, medical researchers will be unable to conduct studies that can improve public health. Without it, pharmaceutical and biotechnology companies will be deprived of information necessary to

effectively comply with federal safety regulations, implement drug recall programs and communicate to prescribers information about innovative, life-saving treatments. In sum, by restraining publication of prescriber-identifiable data, the Maine law takes healthcare in the wrong direction while doing nothing to improve the well-being of Maine's citizens.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337 and 1343(a)(3) and (4), because the action arises under the Commerce Clause, and the First and Fourteenth Amendments to the United States Constitution, and under 42 U.S.C. §§ 1983 & 1988.

10. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c), because plaintiffs' claims arise in this district, and the defendant is a public official located within this district.

THE PARTIES

11. Plaintiff, IMS Health Incorporated ("IMS Health"), is a Delaware corporation with its principal place of business for U.S. operations in Plymouth Meeting, Pennsylvania.

12. Plaintiff, Verispan LLC ("Verispan"), is a Delaware limited liability company with its principal place of business in Yardley, Pennsylvania.

13. Plaintiff, Source Healthcare Analytics, Inc. ("Source Healthcare"), is a Delaware corporation and a wholly-owned subsidiary of Wolters Kluwer Health, Inc., with its principal place of business in Phoenix, Arizona.

14. Defendant, Steven Rowe, is the Attorney General of the State of Maine and the chief legal officer charged with the responsibility of enforcing Maine Public Law 2007, Chapter 460, which amends existing statutes, 22 M.R.S.A. §§ 1711-E, 8704, and 8713 (2007).

OTHER COMMON FACTUAL ALLEGATIONS

The following allegations are common to all of the counts of the complaint:

Publishing Activities of IMS Health Incorporated

15. IMS Health is a publicly traded company that was founded as Intercontinental Marketing Services in 1954. IMS Health is the world's leading provider of information, research and analysis to the pharmaceutical and healthcare industries, with data collection and reporting activities in over 100 countries. The company receives and processes vast quantities of health care data each year. In the United States alone, IMS Health collects information from thousands of sources: pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes millions of records each week. The information collected is then aggregated with other information, analyzed and made available to IMS Health's customers through dozens of services designed to help them drive decisions and shape strategies. All of IMS Health's proprietary databases are composed of patient de-identified data. This means that IMS Health neither uses nor transfers information that contains the identity of patients in any of its subscription services.

16. IMS Health's clients include pharmaceutical companies, biotechnology firms, pharmaceutical distributors, government agencies, consulting organizations, the financial community and others. In addition, IMS Health frequently makes information available without charge to academic researchers (researchers at universities throughout the United States), medical researchers (researchers at the Centers for Disease Control, the Institutes of Medicine of the National Academy of Science, the Mayo Clinic and Memorial Sloan-Kettering), humanitarian organizations (American Red Cross), law enforcement authorities (state attorney generals, U.S. Department of Justice, the U.S. Federal Trade Commission, and the U.S. Drug

Enforcement Administration), and industry observers (journalists). With the aid of IMS Health's vast amount of data, these individuals and organizations are able to track patterns of disease and treatment, conduct outcomes research, implement best practices, and apply health economic analyses. The company's databases are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, efficient pharmaceutical sales and marketing resource allocation, and assessment of drug utilization patterns (*e.g.*, on-and-off label uses and regional variations in physician prescribing behavior).

17. IMS Health's prescriber-level databases are also essential to support research, analysis, development and implementation of practice guidelines and public health policy for the advancement of patient health. Examples of these activities include:

a. Asthma in low income areas. A study in New York used IMS Health's prescriber-level information to examine physician-prescribing patterns in under-served urban areas to determine patterns of under-treatment of patients with asthma. There was substantial evidence that asthma controller medications were underutilized, which reflected issues in both physician education and public perceptions. Feedback on the study findings was provided to physicians to engage them in implementing appropriate public health solutions.

b. Community intervention to reduce overuse of antibiotics. A research study relied on IMS Health's prescriber-level data to complete a pediatric study on the judicious use of antibiotics. The objective of the study was to assess the impact of parent and clinician education on antibiotic prescribing and carriage of penicillin-nonsusceptible streptococcus pneumoniae in children. The study resulted in a multifaceted education program that led to community-wide reductions in antibiotic prescribing.

c. Regional impact of bioterrorist threats on prescribing. Wisconsin

researchers at the Marshfield Clinic Research Foundation used IMS Health's prescriber-level information to determine if the public demand for fluoroquinolones, such as Cipro, post-9/11 bioterrorist threats would spread to communities not directly affected by anthrax scares in New York, New Jersey, Connecticut, Pennsylvania, Virginia, Maryland and Florida.

Publishing Activities of Verispan LLC

18. Verispan is a healthcare information company founded by Quintiles Transnational Corp. and McKesson Corp. Verispan is one of the major providers of healthcare information in the United States. Since its founding as Scott-Levin Associates, Inc. in 1982 and along with its constituent companies formerly known as Kelly-Waldron, SMG, Synergy, and Amaxis, Verispan has served the pharmaceutical and healthcare industries in the United States with an important source of healthcare information. Verispan contracts to receive nearly half of all U.S. prescriptions and nearly one-quarter of all U.S. electronic medical transactions annually. Verispan captures a sample of data from a near-census of U.S. retail pharmacies. By focusing on breadth of data coverage, Verispan is able to improve insight into prescription and medical activity at the national, regional and individual prescriber level.

19. All of Verispan's proprietary databases are composed of patient de-identified data. This means that Verispan neither uses nor transfers information that contains the identity of patients in any of its subscription services. With the aid of Verispan's vast amount of data, the medical, scientific, pharmaceutical and healthcare management communities are able to track patterns of disease and treatment, conduct outcomes research, implement best practices, and apply health economic analyses. The company's databases, including physician-identifiable data, are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, efficient pharmaceutical sales and marketing resource

allocation, and assessment of drug utilization patterns (*e.g.*, on-and-off label uses and regional variations in physician prescribing behavior).

20. Verispan's databases are also essential to the effective implementation of healthcare studies. For example, Verispan's data is currently used by the Department of Health and Human Services through the Food and Drug Administration. The FDA uses Verispan de-identified prescription data to monitor the incidence by which any two dispensed drugs are used with one another. This is used by the FDA as the backing to many interaction studies they perform in assessing the safety of ethical prescription medications. Verispan's data has also been used by many of its clients to effectively identify eligible prescribers for clinical trials. In these cases accurate prescriber level data is crucial to perform accurate and expeditious clinical trials, which may provide critical healthcare options to patients in need of alternative treatment.

Publishing Activities of Source Healthcare Analytics, Inc.

21. Wolters Kluwer is a leading multinational publisher and information services company active in many markets. One division, Wolters Kluwer Health, Inc. ("Wolters Kluwer Health"), a wholly owned subsidiary of Wolters Kluwer U.S. Corporation, is a primary supplier of information to professionals and students in the fields of medicine, nursing, allied health, and pharmacy, as well as entities in the pharmaceutical industry. It produces textbooks, reference products, journals, and other informational materials that professionals employ in the knowledge-intensive, rapidly changing practice of medicine. Source Healthcare Analytics, Inc. ("Source Healthcare"), a wholly owned subsidiary of Wolters Kluwer Health, sells a variety of information products that use "prescriber-identified prescription data," i.e., records that match prescriptions to prescribers. To create these information products, Source Healthcare purchases prescriber-identified data from pharmacies or other originating entities, then aggregates,

analyzes, and packages it for use by subscribers and other customers.

22. Source Healthcare's subscribers and other customers use the data in a broad range of activities. For example, pharmaceutical manufacturers use it to identify doctors who may be interested in their products and who may have patients who would be suitable participants in clinical trials of promising new drugs. Source Healthcare's subscribers and customers use the data to report to governmental agencies, including the FDA, discharging their regulatory and law enforcement responsibilities. Products like Source Healthcare's can help governmental agencies direct drug safety alert letters toward doctors whose prescribing practices make them relevant, and enforce civil and criminal laws against abusive prescribing practices. In addition, a variety of individuals and organizations use the data in research concerning drug usage, interactions, effectiveness, and costs.

The Information at Issue: Prescriber-Identifiable Data

23. In the United States, approximately 1.4 million prescribers are licensed to write prescriptions. Prescriptions are written for approximately 8,000 different pharmaceutical products, and many of these products are dispensed in various forms, strengths, and doses.

24. Prescriptions are dispensed by approximately 54,000 retail pharmacies throughout the United States, as well as other medical facilities licensed to fill prescriptions.

25. Retail pharmacies in the United States are composed primarily of chain pharmacies, independent pharmacies, mass merchandisers and food stores with in-store pharmacies, mail order pharmacies, and long-term care pharmacies.

26. Retail pharmacies acquire prescription data during the regular course of business. For each prescription filled, a record is kept that includes the name of the patient, information identifying the prescriber, the name, dosage and quantity of the prescribed drug, and the date the

prescription is filled. If the pharmacy is part of a larger organization with multiple retail outlets, each outlet's prescription data is ultimately aggregated with data from other outlets and stored in a central location.

27. After retail pharmacies acquire prescription data, they then license, sell, or transfer the data (without disclosing the patient's identity) to health information publishers for two distinct purposes. First, in order to make a profit. Second, they license, sell, or transfer the information to the health information publishers because those companies have developed sophisticated methods of aggregating and analyzing the information in order to make the information useful to entities that devote substantial resources to improving the health and welfare of consumers.

28. The patient de-identified information that the health information publishers purchase from pharmacies and similar entities include: the name of the pharmaceutical product, information identifying the prescriber, the name, dosage and quantity of the prescribed drug, and the date the prescription is filled.

29. Currently, health information publishers collectively acquire, aggregate and analyze information relating to billions of prescription transactions per year throughout the United States.

30. Plaintiffs acquire, license, sell, use, or transfer the information for two distinct purposes. First, to make a profit. Second, to improve public health and welfare by licensing, selling, and transferring it to pharmaceutical companies and to other entities that devote substantial resources to using the information to improve the health and welfare of consumers.

31. Some of the entities to which the plaintiffs license, sell, or transfer the information use the information for advertising, marketing, and promotional purposes. These

entities and others also use the information for other purposes that are not associated in any way with advertising, marketing, and promotional purposes.

32. Plaintiffs strongly believe that the widespread dissemination and use of the prescription information that they gather and analyze improves the health and welfare of consumers.

How the Prescription Information is Gathered & Published

33. Plaintiffs purchase prescriber-identifiable data from participating pharmacies and other sources. To comply with state and federal laws regarding patient privacy, participating pharmacies allow plaintiffs to install software on their computers that encrypts any information identifying the patients before it its transferred to plaintiffs' computers. After patient information is de-identified in this way, a number is assigned to each de-identified patient that permits prescription information to be correlated for each patient but does not allow the patient's identity to be determined. The prescription information is then transferred to the plaintiffs' computers.

34. Plaintiffs obtain all of their prescription information, including information on prescriptions filled in Maine, from computers, with limited exceptions, that are located outside of Maine.

35. Plaintiffs add value to prescriber-identifiable data by combining the data with prescriber reference information contained in their databases. This allows the plaintiffs to, among other things, (a) match each prescription to the correct prescriber, (b) identify and use the correct name of the prescriber, and (c) add address, specialty and other professional information about the prescriber to the prescription data. Prescriber reference files are created using information obtained from various sources, including the American Medical Association's

Physician Masterfile. The AMA's Masterfile contains demographic, educational, certification, licensure, and specialty information for more than 800,000 active U.S. medical doctors (MDs) and over 90% of the doctors of osteopathy (DOs), including members and nonmembers alike.[3] The health information publishers use the patient de-identified prescription data, together with the reference file information, to produce a variety of databases.

36. Plaintiffs use these databases to create a number of different reports and services regarding prescribed pharmaceutical products, some of which include prescriber-identifiable information and some of which is aggregated and reported at a broader geographic level. Plaintiffs then license the information from these reports and services to third parties for many different uses.

37. The patient de-identified prescription data that the plaintiffs supply to their pharmaceutical and biotechnology clients are used for many purposes. The prescription data, for example, are used by these clients to:

a. Prioritize the release of public safety news alerts based on physician prescribing details;

b. Accelerate innovation through insight into the needs and habits of those whose health the new drugs are designed to improve;

c. Determine which products to develop and license and which acquisitions to consider;

d. Disseminate effectively and quickly vital, life-prolonging information to those prescribers for whom the information is relevant and most useful;

e. Allocate effectively valuable, life-prolonging sample medications to those prescribers whose patients need them most and are more likely to use them;

[3] As of July 1, 2006, the AMA has made it possible for all physicians, including those in Maine, to choose whether to prevent the release of prescriber-identifiable information about them to pharmaceutical sales representatives by participating in the Prescribing Data Restriction Program ("PDRP"). *See* www.ama-assn.org/go/prescribingdata.

f. Determine whether a particular prescriber is prescribing products that the pharmaceutical companies have determined to be inappropriate in light of the development of new products that may be more effective, safer, or less expensive;

g. Implement prescription drug recall programs;

h. Evaluate, segment, target, size, compensate and deploy its sales force;

i. Allocate limited marketing resources to individual prescribers in a manner that reduces cost and saves time; and

j. Understand managed care's effect on the U.S. pharmaceutical marketplace.

38. Plaintiffs also provide patient de-identified prescription data without charge to academic researchers, medical researchers, government agencies, industry observers and others for a variety of purposes that are unrelated to the sale of a particular product.

39. Plaintiffs do not sell, market, or promote pharmaceutical products or drugs to prescribers.

40. Patient de-identified prescription information without prescriber-identifiable information is not an adequate substitute for accurate information regarding the actual prescriptions written by individual physicians for many reasons, including: (a) pharmacies fill prescriptions that come from distant prescribers, (b) information from pharmacies frequently does not include accurate zip code information for the prescriber, (c) information from pharmacies does not include the specialty of the prescribers who wrote the prescription, (d) the information is not useful for all of the uses described in paragraphs 37-38 above, and (e) significant errors in the information cannot be ascertained.

History of the Prescription Restraint Law

41. The sponsors of the Prescription Restraint Law have asserted that restrictions on the use or disclosure of prescriber-identifiable prescribing information is necessary for three

reasons: to protect doctors' prescriptions from public scrutiny, to reduce the price of prescription drugs in Maine, and to improve the public health. They have argued that the disclosure of prescriber-identifiable information to pharmaceutical companies gives pharmaceutical sales representatives (also known as "detailers") too much insight into prescriber behavior that often leads to inappropriate confrontation or coercion of prescribers about the products they prescribe.

42. The sponsors of the Prescription Restraint Law have also argued that (a) pharmaceutical sales representatives usually sell new branded drugs, (b) branded drugs are more expensive than generic drugs, and (c) by knowing the behavior of prescribers, the sales representatives will be better equipped to target their advertising and persuade the doctors to prescribe the branded drugs over the less costly generic drugs.

43. These assertions ignore that pharmaceutical sales have occurred for decades and the Prescription Restraint Law does nothing to stop or regulate inappropriate detailing practices. More importantly, the assertions made to justify the enactment of the Prescription Restraint Law make the following unstated assumptions: (a) prescribers, all of whom are highly-educated and licensed healthcare professionals, are incapable of evaluating for themselves, truthful and accurate information regarding their own prescribing practices, rejecting or simply ignoring such information if they do not find it significant; (b) prescribers are unable to consider information from various sources (including information from pharmaceutical companies) to make a professional judgment regarding the most appropriate medication for each patient; (c) higher cost branded pharmaceuticals will always result in higher overall costs of patient care; and (d) if government regulators decide what information should be communicated by pharmaceutical companies, then the cost of prescription drugs to consumers will decline. These are just that – assumptions that are unsupported by experience, evidence, or logic.

44. No studies have been performed that would support the conclusion that the price of prescription drugs would decrease if pharmaceutical companies were unable to use prescriber information in connection with their marketing activities. In fact, the price of prescription drugs may increase because costs associated with marketing pharmaceutical drugs are likely to increase as pharmaceutical companies are unable to focus their resources on the relevant market. In addition, overall healthcare costs are likely to increase because prescribers will have less information regarding the drugs they should be prescribing.

45. The legislative history of the Prescription Restraint Law reflects that the Maine Legislature had intended to enact a law that would have been similar to the New Hampshire law, but when the Legislature learned that the New Hampshire law had been declared unconstitutional, it hurriedly amended the bill to allow the continued licensing, use, sale, transfer or exchange for value of prescriber-identifiable information in prescription records for marketing purposes except information relating to those prescribers who specifically request a prohibition on the continuing licensing, use, sale, transfer or exchange for value of information about their prescribing practices for such purposes. In addition, the Legislature quickly created findings to attempt to support this significantly revised bill, utilizing evidence that had been taken regarding a New Hampshire-style bill.

The Prescription Restraint Law

46. The Maine Legislature passed the Prescription Restraint Law as L.D. 4 on June 19, 2007, and the Governor signed the bill into law on June 29, 2007. The bill became Maine Public Law 2007, Chapter 460, and it amends the existing Sections 1711-E, 8704, and 8713, of Title 22, Maine Revised Statutes Annotated ("M.R.S.A.").

47. Section 1 of Chapter 460 amends 22 M.R.S.A. § 1711-E substantially. It amends

the existing subsections 1, 2, and 3 of § 1711-E, and adds subsections 1-A, 1-B, 2-A, 4, and 5.

48. Subsection 1-A of § 1711-E, as amended, entitled "Findings," states: "The Legislature finds that enactment of this section will assist the State to achieve the following compelling state interests: to improve the public health, to limit annual increases in the cost of health care and to protect the privacy of patients and prescribers in the health care system of this State." It then sets forth six conclusory "findings" without citation to supporting evidence.

49. Subsection 1-B of § 1711-E, as amended, entitled "Purposes," states "It is the intent of the Legislature in enacting this section to achieve the following compelling state interests: to improve public health, to limit annual increases in the cost of health care and to protect the privacy of patients and prescribers in the health care system of this State." Both subsections 1-A and 1-B state that the law is "narrowly and carefully tailored" to address the findings listed in §-1, to achieve the State's purposes listed in § 1-B, and to advance the State's compelling interests.

50. Subsection 2-A of § 1711-E, as amended, entitled "Confidentiality of prescription drug information that identifies the prescriber," is the critical portion of the new law which blocks the flow of protected speech regarding prescribing practices.[4] Subsection 2-A provides as follows:

> Beginning January 1, 2008, a carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection in accordance with subsection 4.

51. The term "marketing" is defined in section 1 as "any of the following activities undertaken or materials or products made available to prescribers or to their employees or agents

[4] Subsection 2 imposes similar restrictions on the flow of prescription drug information that identifies the *patient.* Plaintiffs do not challenge this portion of the law.

related to the transfer of prescription drugs from the producer or seller to the consumer or buyer":

> (1) Advertising, publicizing, promoting or selling a prescription drug;
>
> (2) Activities undertaken for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit or a personal appearance;
>
> (3) Activities undertaken to evaluate or improve the effectiveness of a professional detailing sales force; or
>
> (4) A brochure, media advertisement or announcement, poster or free sample of a prescription drug.

52. Section 1 states that "marketing" does not include: pharmacy reimbursement, formulary compliance, pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, patient care management, utilization review by a health care provider or agent of a health care provider or the patient's health plan or an agent of the patient's health plan, and health care research. Notably, "clinical trials" conducted by manufacturers to test a new drug in accordance with FDA requirements are not excluded from the definition.

53. The term "prescription drug information intermediary" is defined as:

> [A] person or entity that communicates, facilitates or participates in the exchange of prescription drug information regarding an individual or a prescriber. "Prescription drug information intermediary" includes, but is not limited to, a pharmacy benefits manager, a health plan, an administrator and an electronic transmission intermediary and any person or entity employed by or contracted to provide services to that entity.

54. Plaintiffs are entities that communicate, facilitate or participate in the exchange of prescription drug information regarding a prescriber. Thus, they qualify as "prescription drug information intermediar[ies]," such that the prohibitions of subsection 2-A apply directly to them.

55. Subsection 3 of § 1711-E, as amended, provides that a violation of subsection 2-A

is a violation of the Maine Unfair Trade Practices Act.

56. Subsection 4 of § 1711-E, as amended, provides a mechanism by which, beginning October 1, 2007, the board of licensure of a prescriber shall provide as part of the licensure and relicensure process a packet telling the prescriber that prescription drug information that identifies the prescriber is used for marketing purposes by carriers, pharmacies, and prescription drug information intermediaries and that the prescriber may restrict the flow of that information by submitting a form to the licensing board or the Maine Health Data Organization. The licensing board is required to submit to the Maine Health Data Organization on a monthly basis a list of all prescribers who have filed with the licensing board for confidentiality protection. The confidentiality protection information packet must inform the prescriber that filing for confidentiality protection is effective until it is revoked by the prescriber. Subsection 4 also provides that the Department shall assess an annual fee on manufacturers of prescription drugs whose drugs are dispensed through certain State programs to fund the new law.

57. The law also authorizes the boards of licensure and requires the Department of Health and Human Services and the Board of Directors of the Maine Health Data Organization to adopt rules to implement, administer, and enforce the prescriptions restraint requirements.

Violations of the Law are Punishable by Severe Penalties

58. The Prescription Restraint Law provides that a violation of § 1711-E, sub-§ 2-A's restrictions on the flow of prescriber information is a violation of the Maine Unfair Trade Practices Act. 22 M.R.S.A. § 1711-E, sub-§ 3, as amended by P.L. 2007, Ch. 460, § 1.

59. The Maine Unfair Trade Practices Act, 5 M.R.S.A. § 209, authorizes the Attorney General to bring an action in the name of the State against any person he has reason to believe is

using or is about to use an unlawful trade practice. In addition to a temporary or permanent restraining order, a penalty of not more than $10,000 *shall be* adjudged for *each* intentional violation of the Maine Unfair Trade Practices Act established by the Attorney General. 5 M.R.S.A. § 209. Because the plaintiffs acquire and publish millions of discrete pieces of information from regulated records, the Attorney General could seek to impose vast penalties on the plaintiffs if they continued to engage in their ordinary business practices after the effective date of the law.

Damage Inflicted by the Law on Plaintiffs

60. The Prescription Restraint Law imposes serious and irreparable injury on (a) the plaintiffs' use of prescriber-identifiable data in prescription records for any marketing purpose, (b) pharmacies' and other entities' use of prescriber-identifiable data in prescription records for any marketing purpose, (c) pharmaceutical companies, health care researchers, prescribers, and patients, all of whom benefited from the plaintiffs' and other entities use of prescriber-identifiable data in prescription records for marketing purposes.

61. If the plaintiffs cannot use the information other than for purposes identified as permissible in the Prescription Restraint Law, neither the plaintiffs nor any other persons or entities will be able to profitably continue acquiring the information, aggregating the information, analyzing the information, and distributing the information to third parties either for purposes allowed or for purposes prohibited by the Prescription Restraint Law.

62. It is highly probable that a large number of prescribers will elect to invoke the protection of the law because the law was advocated by a significant number of prescribers; prescribers in Maine and in other states have previously expressed their view that they would like to prevent manufacturers from using information about their prescribing practices for

marketing drugs; and Maine will be advising all prescribers, in accordance with the law, that they may elect to invoke the protection of the Prescription Restraint Law when they apply for licenses or license renewal. The law therefore will operate to freeze communication of a large amount of prescriber identifiable information in prescription records.

The Imminent Threat & Reasonable Fear of Enforcement

63. Plaintiffs have concrete plans to engage after January 1, 2008, in activity proscribed by the law: purchasing and selling information showing the prescribing practices of Maine-licensed prescribers in prescription records for marketing purposes, including information about Maine-licensed prescribers who invoke the law.

64. Plaintiffs have a reasonable fear that an action for injunctive relief and damages will be brought by the Attorney General if they execute those concrete plans.

65. After the law was enacted, plaintiffs' counsel wrote to the Attorney General's office to determine whether the plaintiffs, their sources, and their subscribers would be subject to an enforcement action if they continued their existing business practices.

66. To date, the Attorney General has provided no assurances that the law would not be enforced against all of these entities as soon as it becomes effective.

67. It is highly likely that the Attorney General would seek to stop the plaintiffs from violating the law by seeking injunctive relief and, if the law were violated, fines of $10,000 for each violation.

Count I

The Prescription Restraint Law Violates the First Amendment by Prohibiting the Plaintiffs' Commercial Speech

68. Plaintiffs reallege paragraphs 1 through 67 and incorporate them herein by reference.

69. The Prescription Restraint Law restricts commercial speech through its prohibition of the license, use, sale, transfer, or exchange for value of records relative to prescription information containing prescriber-identifiable data for specified "marketing purposes" and expressly excludes from its prohibition the license, use, sale, transfer, or exchange for value of the specified records for "non-marketing" purposes.

70. The Prescription Restraint Law does not directly advance the interests that it purports to serve. Indeed, the statute appears to be taking the most indirect route that it possibly could take to achieve its objectives. Instead of imposing direct regulations on the manner in which pharmaceutical companies market their products or the pricing of the products, the statute attempts to prevent the information that pharmaceutical companies would like to consider in deciding how to market their products from being licensed, used, sold, transferred, or exchanged for value for any of a broad range of commercial purposes, many of which may be unrelated to advertising. The State of Maine may regulate the marketing practices or the pricing decisions of pharmaceutical companies, but it may not, without violating the First Amendment, do so indirectly by imposing restrictions on the dissemination of truthful information used by such companies to make advertising and other decisions in the hope that such indirect regulation will have the intended regulatory affect. There is no evidence, of course, that the Prescription Restraint Law would directly advance any of the justifications that the State may assert justify the legislation. Imposition of direct regulation on the advertising and pricing of pharmaceutical companies itself raises a host of constitutional concerns, but the State should not be permitted to achieve indirectly by suppression of constitutionally protected speech what it may be prohibited from regulating directly.

71. The Prescription Restraint Law also is broader than necessary to accomplish the

interests that it purports to serve. The State of Maine either has failed to consider or has rejected less restrictive alternatives to the Prescription Restraint Law. If it is the State's contention that prescribers are mis-prescribing pharmaceutical products for personal gain, the State can, among other things, take direct action against physicians for engaging in such practices. If it is the State's contention that prescribers are being misled by pharmaceutical companies with false and misleading information, the State can, among other things, impose severe penalties on pharmaceutical companies for doing so. If it is the State's contention that prescribers do not have sufficient information concerning competing generic drugs that are not marketed by pharmaceutical companies, then the State can, among other things, provide additional information to prescribers or require education of prescribers in this regard as a condition of continued licensing. None of these alternatives would require the suppression of constitutionally protected speech in order to achieve the State's objectives.

72. The State recently enacted a statute which requires the Department of Health and Human Services to establish a prescription drug academic detailing program, consisting of education and outreach to prescribers and dispensers regarding the therapeutic and cost-effective use of prescription drugs as issued in peer-reviewed scientific, medical and academic research publications. Me. P.L. 2007, Ch. 327, § 1. This program is a less restrictive alternative which provides for more information to prescribers to allow them to make well-educated decisions for the health of their patients. At a minimum, the academic detailing program should be implemented and its efficacy reviewed before the State can claim that it has no less restrictive alternatives than Chapter 460's ban on the disclosure of truthful information to achieve its goals.

73. The Prescription Restraint Law therefore violates the First and Fourteenth Amendments of the United States Constitution as it is applied to the commercial speech in which

the plaintiffs engage in the regular course of their business.

Count II

The Prescription Restraint Law Violates the First Amendment by Prohibiting the Plaintiffs' Non-Commercial Speech

74. Plaintiffs reallege paragraphs 1 through 67 and incorporate them herein by reference.

75. The Prescription Restraint Law prohibits the license, use, sale, transfer, or exchange for value of records relative to prescription information containing prescriber-identifiable data for "any marketing purpose" and expressly excludes from its prohibition the license, use, sale, transfer, or exchange for value of the specified records for non-marketing purposes. The prohibition extends to substantial non-commercial speech in which the plaintiffs engage.

76. The fact that information may be sold for a profit does not transform the speech into "commercial speech." Newspapers, magazines, and other publishers of information all sell information for a profit; yet their speech is recognized as "non-commercial" because it serves important public purposes unrelated to commercial transactions. Commercial speech is speech that does no more than propose a commercial transaction.

77. When pharmacies and other entities with prescription information sell patient de-identified information to the plaintiffs and when the plaintiffs in turn license, sell, or transfer patient de-identified prescription information to third parties, they are not proposing a commercial transaction; they are conveying truthful information that lawfully is in their possession to a third party that is interested in learning the information and using the information for a myriad of purposes, including both commercial purposes and non-commercial purposes. A substantial amount of the commercial purposes for which the information is obtained are for

profit but are not for the purpose of proposing a commercial transaction.

78. Many of the purposes for which the information is obtained are not for advertising, promotional, or marketing activities, but for purposes that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual healthcare professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. These activities are prohibited as "marketing" under the statute, even though they do not constitute commercial speech.

79. The Prescription Restraint Law restricts non-commercial speech on the basis of its content.

80. The State of Maine lacks a compelling justification for prohibiting non-commercial speech through its prohibition against the license, use, sale, transfer, or exchange for value of records containing prescriber-identifiable data by pharmacies, insurance companies, pharmacy benefits managers, health plans, administrators, electronic transmission intermediaries, and other entities, such as the plaintiffs, for "any marketing purpose."

81. The Prescription Restraint Law is not the least restrictive means of achieving the purpose of the Prescription Restraint Law.

82. In addition, the Prescription Restraint Law is not limited in its operation to the imposition of fines upon violators; it also sets up a system of prior restraint against future speech by allowing a prescriber to censor truthful, important information about that prescriber. Any system of prior restraint comes to this Court bearing a heavy presumption against its constitutional validity. In order to be constitutional, the statute must fit within one of the narrowly defined exceptions to the prohibition against prior restraints and must include procedural safeguards that reduce the danger of suppressing constitutionally protected speech.

The statute does not fit within any recognized category of valid prior restraints, and it does not contain procedural safeguards that are required for a valid system of prior restraints.

83. The Prescription Restraint Law lacks the procedural safeguards that are required to uphold a law that creates a system of prior restraint. Prescribers are empowered to prohibit private parties in *advance* of publication of publishing lawfully-obtained, truthful, and important information about their prescribing practices. In essence, the state has designated each prescriber as the licensor of the pharmacy's right to distribute prescriber-identifiable data, but has defined no criteria to prevent exercise of this unfettered power for improper censorial purposes and no time restraints on when a prescriber would be required to act on a request to publish data pertaining to him or her. Accordingly, the law is an invalid restraint on speech.

84. The Prescription Restraint Law therefore violates the First and Fourteenth Amendments of the United States Constitution facially and as it is applied to the non-commercial speech in which the plaintiffs engage in the regular course of their business.

Count III

The Prescription Restraint Law is Void for Vagueness & Overbreadth

85. Plaintiffs reallege paragraphs 1 through 67 and incorporate them herein by reference.

86. The Prescription Restraint Law is vague and overbroad.

87. The law prohibits the license, use, sale, transfer, or exchange for value of certain information only for certain purposes, but it does not state whether it is the purpose of the acquirer of the information, the provider of the information, the ultimate consumer of the information or some combination of all of these that determines the purpose of the transfer. The statute does not inform a reader how the purpose of a given transaction is to be determined.

88. The law provides that the covered entities may not supply covered data for "any marketing purpose," but it excludes from the definition of "marketing" six delineated purposes. Under this provision, the plaintiffs may acquire covered data from covered entities and sell the data to third parties for, among other things, "patient care management," "utilization review," and "health care research." The statute does not define these terms, and they are subject to broadly varying interpretations.

89. In addition, some of the same activities purportedly excluded from the definition of "marketing" could *also* be undertaken for the purposes delineated as "marketing purposes." For instance, a company may perform health care research for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber. In that instance, it is unclear whether such activities would be included or excluded from the definition of "marketing."

90. Given the vague contours of the coverage of the statute, it unquestionably silences some pharmacies and some health information publishers that will no longer sell information because of the real risk that they will be charged with violating the statute.

91. This law fails to give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he or she may act accordingly. It may trap the innocent by not providing fair warning.

92. The vagueness of the law also creates a risk of arbitrary and discriminatory enforcement by impermissibly delegating basic policy matters to law enforcement officers, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application.

93. The vagueness of the Prescription Restraint Law also is a matter of special

concern for two additional reasons:

a. First, the Prescription Restraint Law is a content-based regulation of speech. The vagueness of such a regulation raises special First Amendment concerns because of its obvious chilling effect on free speech.

b. Second, the Prescription Restraint Law authorizes the imposition of severe penalties. The Attorney General is authorized to prosecute civilly violations of the statute under Maine's Unfair Trade Practices Act, which mandates penalties of up to $10,000 *per violation*. If a violation is defined as the transfer of information contained in a single prescription, a company that transfers only 100 prescriptions could be fined $1,000,000. Plaintiffs obtain, analyze, license, and sell information from thousands of prescriptions of Maine-licensed prescribers each year. If the plaintiffs were to continue their current business practices, they would face civil penalties of several millions of dollars. The severity of these penalties may well cause speakers to remain silent rather than communicate even arguably lawful words, ideas, and images. As a practical matter, this increased deterrent effect, coupled with the "risk of discriminatory enforcement" of vague regulations, poses greater First Amendment concerns than those implicated by civil regulation.

94. The uncertain meaning of the statute will force the plaintiffs to "steer far wider of the unlawful zone than if the boundaries of the forbidden areas were clearly marked."

95. The Prescription Restraint Law accordingly is violating the First and Fourteenth Amendments for vagueness and overbreadth.

Count IV

The Prescription Restraint Law Violates the Commerce Clause

96. Plaintiffs reallege paragraphs 1 through 67 and incorporate them herein by

reference.

97. The Prescription Restraint Law impermissibly regulates conduct occurring wholly outside of Maine.

98. The plaintiff health information publishers are located outside of Maine. They collect prescriber identifiable data relating to Maine prescribers outside of Maine and store this data in databases located outside of Maine. All of the prescriber identifiable data received by the plaintiffs, with rare exceptions, is supplied by companies located outside of Maine. The Prescription Restraint Law makes it illegal for pharmacies and other similar entities to continue providing prescriber identifiable data relating to certain Maine-licensed prescribers to the plaintiffs and for the plaintiffs to continue selling, licensing, or transferring that data to entities that may use it for purposes restricted by the Prescription Restraint Law. As a result, all such data received by the plaintiffs cannot be licensed, transferred, used, or sold anywhere, even outside of Maine.

99. Accordingly, the Prescription Restraint Law violates the Commerce Clause of the United States Constitution.

DEMAND FOR RELIEF

Wherefore the plaintiffs demand:

A. A declaration that the Prescription Restraint Law is unconstitutional, as applied to commercial speech.

B. A declaration that the Prescription Restraint Law is unconstitutional both facially and as applied to non-commercial speech.

C. A declaration that the Prescription Restraint Law is unconstitutional, both facially and as applied because it regulates speech using such vague and overly broad terms which will

result in the silencing of an amount of protected speech that is proportionally vast when compared to the amount of unprotected speech, if any, that the law constitutionally may restrain.

D. A declaration that the Prescription Restraint Law violates the Commerce Clause of the United States Constitution by regulating transactions in commerce that take place wholly outside of the State of Maine.

E. A permanent and preliminary injunction against the enforcement of the Prescription Restraint Law.

F. The costs and attorneys' fees that the plaintiffs have incurred in bringing this action, as is provided for by 42 U.S.C. §1988.

G. Such other relief that the Court may deem to be necessary or appropriate to afford the plaintiffs the full relief to which they are entitled.

Respectfully submitted,

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